Am J Transl Res 2022;14(8):5641-5650
www.ajtr.org /ISSN:1943-8141/AJTR0143171

Original Article

3 liters of polyethylene glycol vs. standard bowel preparation have equal efficacy in a Chinese population: a randomized, controlled trial

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Received March 28, 2022; Accepted July 17, 2022; Epub August 15, 2022; Published August 30, 2022

Abstract: Background: The European Society of Gastrointestinal Endoscopy recommends 4L Polyethylene Glycol (PEG) as the standard regimen for bowel preparation (BP). The current study compared 3L and 4L PEG with regard to their effectiveness, tolerability, and safety among Chinese patients to identify the best bowel cleansing method for this population. Methods: The study employed a prospective, observer-blinded, randomized and controlled design in a high-volume endoscopic center. Consecutive patients undergoing colonoscopy were randomly assigned (1:1) to the 3L-PEG or 4L-PEG group. The quality of bowel cleansing, procedure time, adenoma detection rate (ADR), patient tolerance, and adverse events were compared. Results: A total of 330 patients were included in the study. After exclusions, 160 cases in the 3L-PEG group and 158 cases in the 4L-PEG group were included in the final analysis. The quality of bowel cleansing (Boston Bowel Preparation Scale) for both the whole intestine and each segment had no significant differences between the groups ($P > 0.05$). No significant differences were found with regard to procedure time or ADR. The incidences of adverse events such as nausea ($P = 0.001$), vomiting ($P = 0.002$), and bloating ($P < 0.001$) were lower in the 3L-PEG group. Moreover, there was a higher rate of satisfaction in the 3L-PEG group than in the 4L-PEG group ($P = 0.009$). Conclusions: 3L-PEG bowel cleansing represents an optimal alternative to a 4L-PEG preparation, showing similar efficacy and superior levels of satisfaction, acceptability, and safety among users. We recommend 3L PEG as a routine regimen in the clinical setting for Chinese patients. (ClinicalTrials.gov registration number: NCT03356015, registered in 29 November, 2017, https://www.clinicaltrials.gov/ct2/show/NCT03356015).

Keywords: PEG, colonoscopy, quality of bowel preparation, tolerability

Introduction

Colorectal cancer (CRC) is a major cause of cancer-related morbidity and mortality [1]. The prevalence of colon cancer is rising and poses a global health risk [2]. Nowadays, colonoscopy is widely used for screening, surveillance, and prevention of CRC [3]. High-quality bowel preparation is essential for successful colonoscopy. There is a greater likelihood of incomplete procedures, adverse events, and a reduced likelihood that polyps will be detected if preparation is poor [4]. Ideal bowel cleansing regimens should be both effective and well-tolerated. For patients, bowel preparation requires tolerance first, which can become an effective strategy.

The European Society of Gastrointestinal Endoscopy (ESGE) recommends 4L of split-dose polyethylene glycol (PEG) as the standard regimen for bowel preparation [5]. Because of the different characteristics of Chinese patients (e.g., smaller body size, lower body weight, and different dietary habits), however, large volumes (i.e., 4L) of PEG might be poorly tolerated by the Chinese population, despite ensuring better-quality bowel cleansing. Given these facts, there has been a relative lack of research

in this population. As such, a balance should be maintained between volume and effectiveness. The current study compared the effectiveness, tolerability, and safety of 3L and 4L split-doses with regard to Chinese patients to identify the most suitable method of bowel cleansing for this population.

Methods

Study design

This prospective, randomized, reviewer-blinded, and controlled trial enrolled patients and collected relevant data at the Digestive Endoscopic Centre, Changhai Hospital of Shanghai between December 2017 and February 2018. Our study follows CONSORT guidelines. Two designated, experienced endoscopists (each having completed more than 1,000 endoscopies) performed the colonoscopies. CF-H260AI and CF-H290I endoscopes (Olympus, Japan) were used in this study. All patients were awake during the examination and without analgesia or sedation intervention. Biopsies were performed for suspected polyps and tumors. The final diagnosis was confirmed based on a histopathologic examination performed by pathologists who were unaware of the treatment at Changhai Hospital.

Eligible patients were randomly and blindly assigned to the 3L-PEG group or 4L-PEG group through concealed allocation by a technician. Random numbers were generated using SPSS software V20.0. Allocation concealment was achieved using sequentially numbered sealed opaque envelopes. The technician who generated the randomization table was not involved in the colonoscopy procedure. The endoscopist or nurse were not informed of the patients' preparation methods.

Each patient signed an informed consent document and then received relevant training on bowel preparation by the doctors. The protocol complied with the Declaration of Helsinki and was approved by the Ethics Committee of Changhai Hospital (ClinicalTrials.gov registration number: NCT03356015).

Patient selection

Patients scheduled for colonoscopy were eligible for this study. Additional inclusion criteria were aged from 18 to 75 years, undergoing diagnostic colonoscopy, and providing informed consent.

Patients were excluded from this study if they underwent therapeutic colonoscopy (i.e., colonic polypectomy, endoscopic mucosal resection, or endoscopic submucosal dissection); had acute myocardial infarction over the past 6 months; had severe heart, brain, lung, or kidney comorbidities; had intestinal obstruction; had limited mobility; had inflammatory bowel disease; had previous colon surgery; were pregnant or lactating; had participated in other clinical observational studies; or had participated in other clinical studies in the past 60 days.

Patients who did not come as scheduled for their colonoscopy or did not complete a colonoscopy for any reason after study entry were excluded.

Procedures

(1) PEG (Heshuang, Shenzhen Wanhe Pharmaceutical Co., Ltd., model: 68.56 g/bag, China Food and Drug Administration approval number: H20030827, expiration: 36 months) was the drug used in this study. (2) Bowel preparation regimens: Patients in the 4L-PEG group were instructed to take two split doses. The patients were advised to take the first 2L dose (all of the contents of two bags of PEG, dissolved and mixed in 2,000 mL of clear warm water) at 19:00 the night before the examination by drinking 250 mL every 15 minutes and completing the dose within 2 hours. They were advised to take the second 2L dose 4-6 hours before the examination following the same procedure as the first dose.

Patients in the 3L-PEG group were instructed to take two split doses. The patients were advised to take the first 1L dose (all of the contents of one bag of PEG, dissolved and mixed in 1,000 mL of clear warm water) at 19:00 the night before the examination by drinking 250 mL every 15 minutes and completing the dose within 1 hour. They were advised to take the second 2L dose (all of the contents of two bags of PEG, dissolved and mixed into 2,000 mL of clear warm water) 4-6 hours before the examination by drinking 250 mL every 15 minutes and completing the dose within 2 hours.

Moreover, patients were instructed to have little to no residue and maintain a semi-liquid diet (e.g., porridge and noodles; no vegetables or fruits) during the day before the examination. In addition, the patients were instructed to fast beginning at 19:00 the night before the examination. The patients were able to engage in light exercise during dosing to reduce discomfort such as nausea, vomiting, and bloating.

Body mass index (BMI) was calculated using height and weight. Participants were asked to complete a study-specific questionnaire that included information such as age, sex, constipation, history of abdominal surgery, history of diabetes, history of hypertension, and other endoscopy-related indicators such as endoscopic insertion success rate, insertion time, and withdrawal time. Insertion time was defined as the time from endoscopic insertion into the anus to advancement to the caecum. Withdrawal time was defined as the time from endoscopic withdrawal from the caecum to the anus, excluding the time of the biopsy. The same nurse or doctor recorded the data. In addition, gastrointestinal symptoms during bowel preparation such as nausea, vomiting, abdominal pain, bloating, and discomfort during endoscopy were recorded. Patient satisfaction regarding bowel preparation and willingness to undergo the same bowel preparation in the future were evaluated.

Evaluation measures

The primary evaluation measure was the Boston Bowel Preparation Scale (BBPS) score [6, 7]. The entire colon was evaluated in three segments [8]: right colon (caecum and ascending colon), transverse colon (liver and splenic flexures), and left colon (descending colon to rectum). The BBPS is a 9-point scale used to evaluate the quality of a bowel preparation and was used several times in our previous studies [9, 10], where 0 denotes a colon filled with faeces and faecal residue, resulting in the termination of the colonoscopy; 1 represents the presence of a large amount of faeces and faecal residue, obscuring some of the intestines; 2 denotes a small amount of faeces and faecal residue, with no major effect on intestinal visibility; and 3 represents a clean intestine with no faeces or faecal residue. All ratings were performed after bowel irrigation and aspiration. High-quality bowel preparation was defined as a total BBPS score of ≥ 6. Inadequate bowel preparation was defined as a total BBPS score of < 6 [11]. The secondary measure was the adenoma detection rate (ADR), which was defined as the percentage of participants found to have colon adenoma, which was histologically confirmed by at least one colon polyp [9]. Additional measures to be recorded were endoscopic insertion time and withdrawal time. Insertion time was defined as the time from endoscopic insertion into the anus to advancement to the caecum. Withdrawal time was defined as the time from endoscopic withdrawal from the caecum to the anus, excluding the time of biopsy. The same doctor or nurse recorded all of the data. Patient satisfaction regarding bowel preparation was rated using a Likert scale, where 1: unsatisfactory, 2: fair, 3: satisfactory. Patient willingness to undergo the same bowel preparation in the future was rated as “yes” or “no”.

Sample size estimate and statistical analysis

Our previous experience showed that the BBPS score is ≥ 6 in approximately 85% of patients undergoing regular bowel preparation. For a statistical power of ≥ 80% and a level of 0.05 (one-sided), 158 participants were expected to enroll in each group to improve the percentage of participants with a BBPS score of ≥ 6 by 10% in the 4L-PEG group over the 3L-PEG group. Given a drop-out rate of 5%, 165 participants were planned for enrolment in each group, for a total of 330 participants. Analyses were performed to compare the efficacy of 3L-PEG vs. standard regimen. Categorical variables were analysed using the Chi-square test or Fisher exact test according to appropriate situation. Continuous variables were expressed as mean ± standard deviations and analysed utilizing Mann-Whitney U test or Student’s *t*-test. Logistic regression was applied to identify impact factors of inadequate BP. Subgroup analysis were conducted with the following variables: age, BMI, gender, smoking, drinking, comorbidities, constipation, abdominal or pelvic surgery history and colonoscopy history. SPSS v20.0 (SPSS, Chicago, IL, USA) was used for data processing. $P < 0.05$ was considered significant.

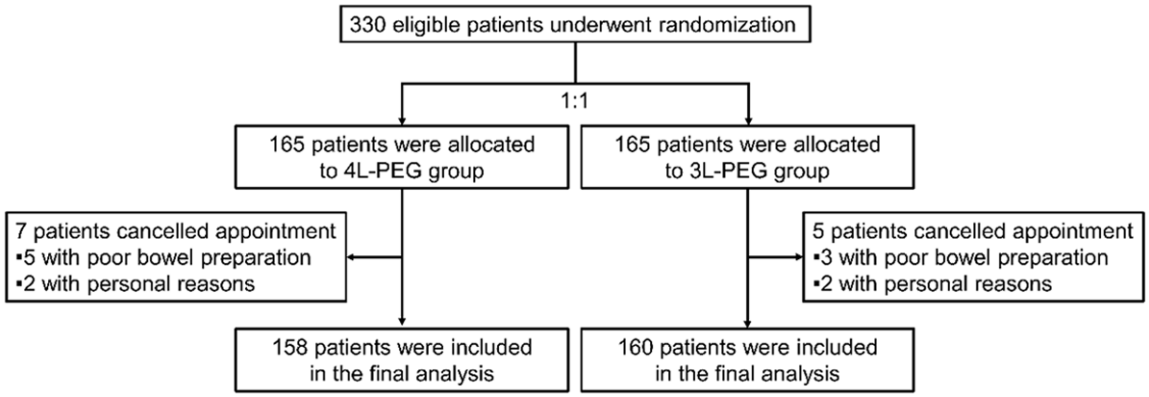


Figure 1. Study flow diagram. PEG, Polyethylene glycol.

Results

Study population

The study flow chart is shown in **Figure 1**. Between December 2017 and February 2018, a total of 330 participants were enrolled in this study. Of these patients, twelve did not complete the examination, including seven participants in the 4L-PEG group (poor bowel preparation: n = 5, personal reasons: n = 2) and five in the 3L-PEG group (poor bowel preparation: n = 3, personal reasons: n = 2). Therefore, 318 participants completed the examination (4L-PEG group: n = 158, 3L-PEG group: n = 160).

Baseline characteristics

The clinical and demographic characteristics are shown in **Table 1**. Overall, participants in this study were 51.1 ± 13.0 years (range, 18-75), 51.6% male and with mean BMI of 22.9 ± 2.9 kg/m^2. No significant differences were observed between the 4L-PEG and 3L-PEG groups with regard to age (51.3 ± 13.4 vs. 50.9 ± 12.5, P = 0.656), gender (female: 46.8% vs. 50.0%, P = 0.572), BMI (22.9 ± 3.1 vs. 22.9 ± 2.6, P = 0.869), or indications for colonoscopy (P = 0.131).

Efficacy of bowel cleansing

The bowel preparation quality assessment is shown in **Table 2**. The results showed that the adequacy rates were 81.9% and 78.5% in the 3L-PEG and 4L-PEG groups, respectively (P = 0.448). No significant differences were observed between the 4L-PEG and 3L-PEG groups with regard to total BBPS score (4L vs. 3L, 6.5 ± 1.2 vs. 6.7 ± 1.2, P = 0.323) or segmental BBPS scores (4L vs. 3L, right colon: 2.1 ± 0.5 vs. 2.1 ± 0.4, P = 0.585; transverse colon: 2.2 ± 0.5 vs. 2.2 ± 0.6, P = 0.961; left colon: 2.2 ± 0.6 vs. 2.3 ± 0.5, P = 0.647).

Data associated with procedures and adverse events

The procedure-related data and adverse events are shown in **Table 3**. In terms of incorrect diet restriction, no difference was shown in the two groups (4L vs. 3L, 10.1% vs. 11.2%, P = 0.746). In the 4L-PEG group, 6.7% of participants' interval of preparation-to-colonoscopy was ≥ 8 h and this ratio was 9.1% in the 3L-PEG group (P = 0.204). There was also no difference in preparation-to-colonoscopy interval between the two groups (P = 0.698). The patient satisfaction rates with "fair" or "satisfactory" were 89.2% for the 4L-PEG group and 97.5% for the 3L-PEG group, and this difference was significant (P = 0.008). Regarding patient willingness to undergo the same bowel preparation as needed in the future, 86.7% in the 4L-PEG group, and 96.2% in the 3L-PEG group chose "yes"; this difference was significant (P = 0.002).

In the **Table 3**, the rates of nausea (22.8% vs. 9.4%, P = 0.001), vomiting (19.0% vs. 7.5%, P = 0.002), and bloating (25.9% vs. 6.2%, P < 0.001) were significantly higher in the 4L-PEG group than the 3L-PEG group.

Subgroup analysis

In **Figure 2**, the effects of the two PEG methods on adequate BP were estimated respectively. Overall, there was no significant difference in

Table 1. Baseline characteristics

Variable	Overall	3L-PEG group (n = 160)	4L-PEG group (n = 158)	*P*-value
Age (y)	51.1 ± 13.0	50.9 ± 12.5	51.3 ± 13.4	0.656
BMI (kg/m^2)	22.9 ± 2.9	22.9 ± 2.6	22.9 ± 3.1	0.896
Female	154 (48.4%)	80 (50.0%)	74 (46.8%)	0.572
Smoking	55 (17.3%)	30 (18.8%)	25 (15.8%)	0.49
Drinking	69 (21.7%)	33 (20.6%)	36 (22.8%)	0.64
DM	30 (9.4%)	15 (9.4%)	15 (9.5%)	0.971
Hypertension	64 (20.1%)	33 (20.6%)	31 (19.6%)	0.823
CAD	12 (3.8%)	8 (5.0%)	4 (2.5%)	0.248
Cirrhosis	3 (0.9%)	0 (0.0%)	3 (1.9%)	0.121
Constipation	100 (31.4%)	49 (30.6%)	51 (32.3%)	0.751
Family history of colon cancer	34 (10.7%)	16 (10.0%)	18 (11.4%)	0.688
Prior history of colonoscopy	135 (42.5%)	67 (41.9%)	68 (43.0%)	0.834
Previous abdominal or pelvic surgery	93 (29.2%)	42 (26.2%)	51 (32.3%)	0.237
Indication for colonoscopy				0.131
Diarrhea	20 (6.3%)	13 (8.2%)	7 (4.4%)	
Abdominal pain	62 (19.5%)	37 (23.4%)	25 (15.6%)	
Rectal bleeding	61 (19.2%)	25 (15.8%)	36 (22.5%)	
Anemia	4 (1.3%)	4 (2.5%)	0 (0.0%)	
Weight loss	3 (0.9%)	2 (1.3%)	1 (0.6%)	
Increase of CEA	8 (2.5%)	4 (2.5%)	4 (2.5%)	
Changes in stool form or frequency	26 (8.2%)	14 (8.9%)	12 (7.5%)	
Surveillance after endoscopic polypectomy	50 (15.7%)	24 (15.2%)	26 (16.2%)	
Health checkup	48 (15.1%)	18 (11.4%)	30 (18.8%)	
Others	36 (11.3%)	17 (10.8%)	19 (11.9%)	
Timing of colonoscopy, n (%)				0.961
Morning	223 (70.1%)	112 (70.0%)	111 (70.3%)	
Afternoon	95 (29.9%)	48 (30.0%)	47 (29.7%)	

Data are presented as mean ± standard deviation or number (percentage) as appropriate. BMI, Body mass index; DM, Diabetes mellitus; SD, Standard deviation; CAD, Coronary artery disease; CEA, Carcinoembryonic antigen.

Table 2. Outcomes of bowel preparation in the two groups

Variables	3L PEG group (n = 160)	4L PEG group (n = 158)	*P* value
Adequate BP	131 (81.9%)	124 (78.5%)	0.448
Adequate BP in segmental colon[a]			
Right-side colon	135 (84.4%)	126 (79.7%)	0.282
Transverse colon	150 (93.8%)	141 (89.2%)	0.123
Left-side colon	147 (91.9%)	139 (88.0%)	0.248
BBPS score	6.7 ± 1.2	6.5 ± 1.2	0.323
Right-side colon	2.1 ± 0.4	2.1 ± 0.5	0.585
Transverse colon	2.2 ± 0.6	2.2 ± 0.5	0.961
Left-side colon	2.3 ± 0.5	2.2 ± 0.6	0.647

Data are presented as mean ± standard deviation or number (percentage) as appropriate. PEG, Polyethylene glycol; BBPS, Boston Bowel Preparation Scale; BP, Bowel preparation. [a]Adequate BP in segmental colon was defined by segmental BBPS ≥ 2.

the two groups (inadequate BP risk, 3L as reference vs. 4L, odds ratio [OR]: 1.231, 95% confidence interval [CI]: 0.708-2.142). In the subgroup analyses, no difference in the adequate BP was observed in the two groups.

Discussion

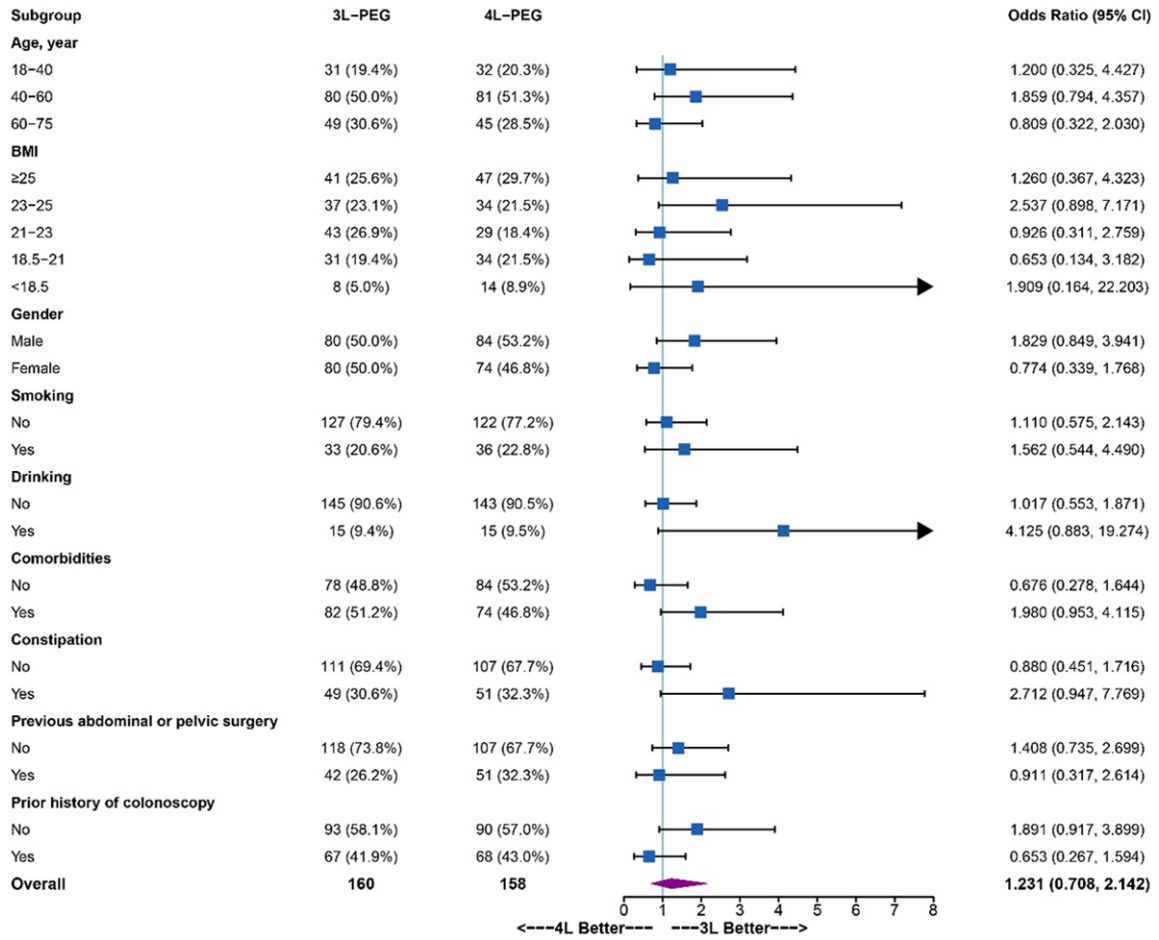
Colorectal cancer (CRC) is one of the most common malignant tumours. The prognosis of advanced CRC is poor; therefore, early detection and treatment play key roles in improving

Table 3. Procedure-associated values and adverse events in the two groups

Variable	3L PEG group (n = 160)	4L PEG group (n = 158)	*P* value
Incorrect diet restriction	18 (11.2%)	16 (10.1%)	0.746
Preparation-to-colonoscopy interval (h)	5.5 ± 1.3	5.6 ± 1.6	0.698
Preparation-to-colonoscopy interval ≥ 8 h	15 (9.1%)	11 (6.7%)	0.204
Cecal intubation time (min)	7.85 ± 6.49	8.45 ± 6.91	0.439
Withdrawal time (min)	7.08 ± 2.86	6.65 ± 2.61	0.179
Diagnosis			0.2
Normal	116 (72.5%)	106 (67.1%)	
Adenoma	31 (19.4%)	38 (24.1%)	
Carcinoma	1 (0.6%)	0 (0.0%)	
IBD	0 (0.0%)	2 (1.3%)	
Others	12 (7.5%)	12 (7.6%)	
Adverse events	32 (20.0%)	79 (50.0%)	< 0.001
Nausea	15 (9.4%)	36 (22.8%)	0.001
Vomiting	12 (7.5%)	30 (19.0%)	0.002
Bloating	10 (6.2%)	41 (25.9%)	< 0.001
Abdominal pain	1 (0.6%)	1 (0.6%)	0.993
Willingness to repeat BP	154 (96.2%)	137 (86.7%)	0.002
Satisfaction			0.008
Unsatisfactory	4 (2.5%)	17 (10.8%)	
Fair	151 (94.4%)	138 (87.3%)	
Satisfactory	5 (3.1%)	3 (1.9%)	

Data are presented as mean ± standard deviation or number (percentage) as appropriate. PEG, Polyethylene glycol; BP, Bowel preparation; IBD, Inflammatory bowel disease.

patient prognosis. Colonoscopies are essential for the diagnosis and treatment of CRC. When used as a CRC screening tool, colonoscopies contribute to the early detection of cancer and the resection of precancerous lesions such as adenoma [12-17], thereby reducing CRC-related morbidity and mortality rates. However, colonoscopies are invasive and associated with significant discomfort and certain risks; furthermore, they cause fear and anxiety among most patients. Successful colonoscopies require extensive colonoscopic experience, high-quality colon cleansing, and patient cooperation [18]. Inadequate bowel preparation is considered as the most important adverse factor for colonoscopies because it prolongs insertion time, causes more discomfort, and is associated with a low ADR and potentially earlier repeat colonoscopy [19, 20]. Therefore, researchers have focused on optimal bowel preparation strategies. Current clinical guidelines recommend several intestinal cleansing regimens, including 3L-PEG (see the guidelines for intestinal preparation related to digestive endoscopy in China), 4L-PEG (the ESGE), and high-permeability low-volume solution (e.g., magnesium sulphate, mannitol, and sodium phosphate oral solution). In 2010, the US Food and Drug Administration disclosed that oral phosphate-containing intestinal cleansing solution can cause hypovolemia or severe electrolyte imbalance in patients scheduled for colonoscopy [21]; it might even cause renal failure in patients with phosphatase nephropathy. The 2013 ESGE Guidelines for Bowel Preparation for Colonoscopy [5] recommend a 4-L PEG split-dose regimen for routine bowel preparation. PEG binds to water molecules in the colon through its hydrogen bonding site, thereby increasing faecal water content. Moreover, as an isotonic whole-intestinal lavage solution, PEG maintains the approximate isotonic condition of the intestine. PEG is not rapidly absorbed or metabolised; thus, it does not affect fluid or electrolyte balance. In addition, it does not produce acid or gas and is mild and non-irritating. Furthermore, it is not rapidly absorbed by the intestinal mucosa, nor can it cause an excessive exudation of body fluid, dehydration, or weight loss [22]. PEG is recom-



mended as a first-line bowel preparation solution given the physical satisfactory cleansing effects associated with its high volume. A recent meta-analysis [23] showed that a 4-L PEG split-dose regimen was superior to other bowel cleansing regimens for bowel preparation. However, no studies have investigated whether this high-volume bowel preparation regimen, typically used for European and American populations, is suitable for Asians who are often smaller.

A high-volume PEG solution helps ensure high-quality bowel cleansing; however, it inevitably affects tolerability. In fact, bowel preparation regimens with poor tolerability negatively affect the quality of bowel preparation. From the perspective of patients, any bowel preparation regimen must first have acceptable tolerance to become an effective product. Fayad et al [24] showed that BMI was an independent factor for the quality of bowel preparation. Intense bowel preparation regimens are recommended for patients with high BMIs. Thus, research is needed to investigate whether the volume of the cleansing solution can be reduced in Asian populations with lower BMIs, while maintaining the quality of the bowel preparation. If low-volume bowel cleansing achieves the same bowel preparation quality, then it might improve patient experiences, reduce drug costs, and provide a better option. To this end, we conducted the current randomized controlled clinical study to evaluate the effectiveness, tolerability, and safety of the ESGE-recommended 4-L PEG split-dose regimen versus a 3-L PEG split-dose regimen that is used for clinical trials in China for bowel preparation.

In this study, the 3L-PEG and 4L-PEG split-dose regimens demonstrated similar bowel preparation quality in the Chinese population. The 3L-PEG split-dose regimen was superior to the 4L-PEG split-dose regimen in terms of patient satisfaction, tolerability, and safety. Five of the 330 patients enrolled, including five patients in the 4L-PEG group and three patients in the 3L-PEG group did not undergo colonoscopy because they were unable to take the prescribed high-volume PEG within the specified timeframe (i.e., they took less than 75% or vomited more than 25% of the prescribed dose). The 3L-PEG group demonstrated better tolerability than the 4L-PEG group, although this difference was not significant. Of the patients included in the analysis, the clinical characteristics (sex, age, BMI, indications for examination) of the patients in 4L-PEG and 3L-PEG groups were consistent; no significant between-group differences were observed with regard to endoscopic insertion success rate, insertion time, withdrawal time, or ADR. Moreover, no significant between-group differences were observed with regard to the quality of bowel preparation, including the overall and segmental BBPS, bubble rate scores, or the percentage of patients with adequate bowel preparation (BBPS score ≥ 6). Importantly, the patient satisfaction rate was 97.5% in the 3L-PEG group, which was significantly higher than that of the 4L-PEG group (vs. 89.2%; $P = 0.008$). Furthermore, the rates of nausea, vomiting, and bloating were significantly lower in the 3L-PEG group than in the 4L-PEG group.

Zhao et al [25] evaluated the effect of three oral PEG regimens on bowel preparation before colonoscopy. Their results showed that the 4L-PEG split-dose regimen was superior to the 3L-PEG split-dose regimen or the 4L-PEG single-dose regimen, indicating that the 4L-PEG split-dose regimen achieved better cleansing results. However, these findings differ from those of the present study. This discrepancy might be related to the following factors. Zhao et al enrolled patients aged 18 to 60, whereas this study enrolled patients aged 18 to 75. Thus, the patient population of Zhao et al was younger and showed better tolerability for high-volume regimens, which contributed to better cleansing results. In the subgroup analysis of our study, we found that in different age groups (18-40 years, 40-60 years, and 60-75 years), there was no difference in the adequate bowel preparation between the two regime methods (**Figure 2**). Moreover, Zhao et al measured weight but not BMI; BMI is an independent factor for bowel preparation quality. Patients with higher BMIs might require a higher volume of cleansing solution. The sample size of Zhao et al was relatively small (67, 54, and 59 patients in each of the three groups), which might have contributed to different conclusions compared to the current study if the mean BMI were relatively high. In addition, Zhao et al did not evaluate tolerability or adverse reactions. Future research should evaluate the effect of the 3L-PEG single-dose regimen versus the 4L-PEG single-dose regimen. In the current study, we did not monitor chemistry (electrolytes) or renal function after bowel preparation; however, no patient experienced any serious adverse reaction.

In summary, the 3L-PEG regimen was equally effective for bowel preparation and showed better tolerability and safety than the 4L-PEG regimen in a Chinese population. Thus, the former treatment might be an acceptable alternative to the latter regimen. We recommend using a 3-L PEG split-dose regimen for routine bowel preparation before colonoscopy in Chinese patients.

Limitations

This study was conducted in a single center, which might cause bias in results. The safety and efficacy of 3L-PEG demands further muticenter randomized trials.

Conclusions

3L-PEG bowel cleansing represents an optimal alternative to a 4L-PEG preparation for Chinese people, showing a similar efficacy and superior levels of satisfaction, acceptability, and safety among users. We recommend 3L PEG be a routine regimen for Chinese patients. (ClinicalTrials.gov registration number: NCT0335-6015, registered in 29 November, 2017, https://www.clinicaltrials.gov/ct2/show/NCT0-3356015).

Acknowledgements

The work was funded by Hainan Provincial Natural Science Foundation of China (No.

821RC733) and Hainan Health Industry Scientific research Project (20A200397, 21-A200294). The funding source of the study had no role in study design, data collection, analysis, interpretation or writing the report.

Each patient signed the informed consent document and then received relevant training on bowel preparation by the doctors. The protocol complied with the Declaration of Helsinki and was approved by the Ethics Committee of Changhai Hospital (ClinicalTrials.gov registration number: NCT03356015).

Disclosure of conflict of interest

None.

Abbreviations

PEG, Polyethylene glycol; BP, Bowel preparation; ADR, Adenoma detection rate; BBPS, Boston Bowel Preparation Scale; ESGE, European Society of Gastrointestinal Endoscopy; BMI, Body mass index; CRC, Colorectal cancer.

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